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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,499	07/07/2005	Hisakazu Hojo	050412	2008

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EXAMINER	
BEKKER, KELLY JO	
ART UNIT	PAPER NUMBER
1781	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,499	HOJO ET AL.	
	Examiner	Art Unit	
	KELLY BEKKER	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-7, and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-7, and 9-12 remain pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-7, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhadiya et al (US 6,811,800 B2) as evidenced by Mallangi et al (US 6,039,986). The references and rejection are incorporated herein and as cited in the office action mailed December 17, 2010.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luhadiya et al (US 6,811,800 B2) as evidenced by Mallangi et al (US 6,039,986), further in view of Hojo et al (US 6,254,905 B1). The references and rejection are incorporated herein and as cited in the office action mailed December 17, 2010.

Alternatively, claims 1-3, 5-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhadiya et al (US 6,811,800 B2) as evidenced by Mallangi et al (US 6,039,986) and in view of Hojo et al (US 6,254,905 B1). The references and rejection are incorporated herein and as cited in the office action mailed December 17, 2010.

Claims 1-3, 5-7, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojo et al. (US 6254905 B1) in view of the combination of Koumarianos (US 6488957) and Grossman (About.com, "Facts About Iron" pages 1-5 http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html) and Klahorst ("Calcium, An Important Nutrient" pages 1-5 http:www.ifanca.og/newsletter/2001_05.htm) and Fennema (Food Chemistry, 2nd Edition, pages 778 and 779). The references and rejection are incorporated herein and as cited in the office action mailed December 17, 2010.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 10, and 11 of U.S. Patent No.6,254,905 B1 ('905). The references and rejection are incorporated herein and as cited in the office action mailed December 17, 2010.

Response to Arguments

Applicant's arguments filed March 14, 2011 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a stabilization process) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The present claims are directed towards a food additive composition which is obvious over the cited references of record; the instant claims do not require a stabilization method.

Applicant argues that Luhadiya teaches of a soluble calcium and not a hardly soluble compound as instantly claimed. Applicant's argument is not convincing. As stated previously, Luhadiya teaches that the calcium source is calcium carbonate (Column 8 lines 40-44). As Luhadiya teaches of the same organic calcium compound disclosed and claimed (claim 3), calcium carbonate, one of ordinary skill in the art would expect that the compound of Luhadiya inherently have the same solubility as the inorganic compound instantly claimed.

Applicant argues that Luhadiya teaches 100parts by weight of chelating agent to the calcium component, which is above the 0.001 to 5 parts instantly claimed, and that such a difference is critical as shown in applicant's specification comparative examples 2, 8, 22, and 28. Applicant's argument is not convincing as the claims recite 0.01 to 5 parts by weight of at least one chelating agent and thus do not recite the parts by weight of the calcium component, and suggest the inclusion of additional chelating agents, which would make the total amount of chelating agents able to be above the instantly claimed range. Additionally, as previously stated, the teachings of Luhadiya are more broad than the instantly claimed part ratios, however, the teachings of Luhadiya clearly encompass the claimed part ratios and the determination of a known ingredient within a known range would have been obvious and routine determination to one of ordinary skill in the art. Luhadiya teaches that the food additive composition comprises a variety of embodiments in mammalian milk, including up to 3100ppm additional soluble calcium, about 0.002-2.5% of an added stabilizer, and 0-0.5% of a chelating agent (column 4 lines 60-67); up to 2500ppm additional soluble calcium, about 0.002-1% added

stabilizer, and about 0-0.35% chelating agent (Column 5 lines 1-6); and up to 2200ppm additional soluble calcium, about 0.005-0.5% added stabilizer, and about 0-0.15% chelating agent (Column 5 lines 6-12); Thus encompassing an embodiment (with 2200ppm additional calcium) of an additive comprising 100 parts of at least one organic soluble calcium compound, 2.27-227 parts stabilizer, and 0-68 parts of a chelating agent. Luhadiya teaches that the food additive composition comprises a variety of embodiments in plant/vegetable derived milk, including up to 4500ppm additional soluble calcium, about 0-2.5% stabilizer, and about 0.01-1% chelating agent (Column 5 lines 41-47); up to 2500ppm additional soluble calcium, about 0-1% stabilizer, and about 0.04-0.7% chelating agent (Column 5 lines 47-54); and up to 2100ppm additional soluble calcium, about 0-0.5% stabilizer, and about 0.08-0.5% chelating agent (Column 5 lines 54-60); Thus encompassing an embodiment (with 2100ppm additional calcium) of an additive with a vegetable derived component, 100 parts of at least one organic soluble calcium compound, 0-555.5 parts of a stabilizer, and 2.2-222 parts of a chelating agent.

Applicant argues that the office's calculations are in error as the calculations are based on a calcium fortified mammals milk and not on a food additive composition. Applicant's argument is not convincing. As previously stated, Luhadiya teaches of a food additive by teaching of a calcium fortified protein containing beverage, including milks, which can be easily incorporated into other food or beverage products (abstract, column 3 lines 47-50, examples 5 and 7 and claims 4, 12, 14, 25, 26); in other words, the milk as taught by Luhadiya is considered an additive as instantly claimed.

In response to applicant's argument that Mallangi does not teach the calcium ion concentration claimed and exceeds an upper limit of 5 parts by weight of at least one chelating agent, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that Luhadiya does not teach a calcium ion concentration of 0-10. Applicant's argument is not convincing as the instantly claimed limitation is an obvious result effective variable established by the references of record. As previously stated, it would have been obvious to one of ordinary skill in the art for the calcium enriched milk additive as taught by Luhadiya to contain as low as an amount as possible, including as low as 0%, calcium ions, in order to ensure that there were no free calcium ions to destabilize the milk proteins in the additive composition; to do so would be obvious to one of ordinary skill in the art as it was well known in the art, as evidenced by Mallangi, for protein destabilization, e.g. coagulation and precipitation, in materials, such as milk, to be mainly attributed to free calcium ions in the system (Column 1 lines 26-33).

Applicant argues that the references do not teach the calcium ion concentration as 0-10 and that Hojo specifically teaches away from such an embodiment as Hojo teaches that a calcium ion of less than 10 causes unstable ions. Applicant's argument is not convincing as Hojo (Column 8 lines 34-43) teaches that the calcium ion concentration is balanced for *stability and preventing damage of the proteins and gelling of the food composition*; Hojo teaches that too little can cause instability and that too much can cause damage to the food proteins and gelling; Hojo teaches that the calcium ion concentration as about 10-500, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion. Thus, as previously stated, it would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease the calcium ion concentration at or below 10 if at levels at and below 10 the composition was stable and in order to ensure that protein destruction and gelling of the food composition was prevented. To balance a known composition based on known effects and needs would have been obvious and routine determination of one of ordinary skill in the art at the time the invention was made. Furthermore, the only reason Hojo teaches a minimum calcium ion concentration of 10 is because of the calcium agent instability; and as the problem of metal ion stability was known to be specifically addressed with the use of chelating agents, including citric acid and its derivatives, which react with metallic ions

to form stable complexes in foods, the decrease of the calcium ion concentration below 10 in order to prevent damage to the proteins and gelling of the food composition as taught by Hojo, wherein the calcium ion agent was stabilized through the use of a chelating agent, as was well known in the art, as taught by Fennema, would have been obvious and within the routine determination to one of ordinary skill in the art. To use a chelating agent and to determine an appropriate amount and type of a known chelating agent would have been further obvious and routine determination to one of ordinary skill in the art.

Applicant argues that the references do not teach ferrous gluconate as a chelating agent. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, ferrous gluconate was a known chelating agent.

Applicant argues that there is no motivation to use Koumarionos calcium citrate to enhance nutritional value since Hojo already has calcium. The examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Hojo teaches that the food additive may contain ferrous gluconate or sodium iron citrate i.e. a gluconate or citrate chelating agent as instantly claimed (Column 11 lines 4-8); Koumarianos teaches that the food additive composition contains minerals, including iron and that the amount of the mineral in the food additive composition is determined based on the recommended daily dosage (Column 5 lines 8-17); Grossman teaches that the recommended daily amount of iron in 2001 for males ranged from 8-11mg per day and for females 8-18 mg per day (page 3); and Klahorst, page 2, teaches that the recommended daily amount of calcium in 2001 was 1000-1300

mg per day. Thus, Hojo teaches the use of the calcium and the secondary references are simply relied upon for teaching recommended amounts in the art. As previously stated, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an amount of the ferrous gluconate and/or sodium iron citrate and thus an amount of chelating agent in the additive composition depending on the recommended daily amounts of iron and the amount of iron desired in the final composition as taught by Koumarianos. It would have been further obvious to one of ordinary skill in the art at the time the invention was made for the vitamins and minerals in the food additive, including calcium and iron, to be included in the full recommended daily amounts so that when consuming the food additive the consumers would not be required to take other additives to obtain complete daily fulfillment of the said vitamins and minerals. Thus, one would have been further motivated to include an amount of iron to calcium in the nutritional additive composition based upon the recommended daily amounts of iron and calcium, so that the nutritional additive would fulfill the requirements for both minerals simultaneously; and as the RDA of calcium: iron was 1300:8 or 100:0.6 to 1000:18 or 100:1.8 as taught by Grossman and Klahorst, at the time the invention was made, one would have been motivated to include 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate, i.e. an iron source, per 100 parts of calcium carbonate, i.e. a calcium source. Thus, the composition as taught by Hojo would comprise 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate which are chelating agents as instantly claimed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY BEKKER whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kelly Bekker/
Primary Examiner
Art Unit 1781